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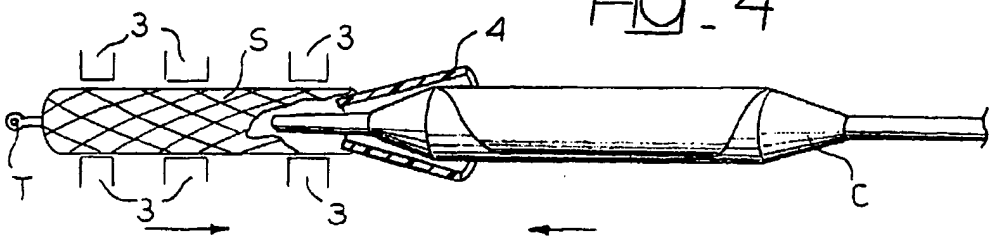
(54) Process for coupling an angioplasty stent to a corresponding insertion element, and kit thus formed

(57) A process for setting an angioplasty stent (S) on a corresponding insertion element (C), in which said angioplasty stent is subjected to an action of radial contraction, envisages that the stent (S) will be subjected to the action of radial contraction before being placed on said insertion element (C). Preferably, the action of radial contraction is carried out in such a way as to bestow on the stent (S) a given diametral dimension (d2) at least marginally smaller than the homologous diametral dimension of the insertion element (C), which typically consists of a balloon catheter. After the stent (S) has been set on the insertion element (C), in the structure of the stent there remain residual states of constraint which act in the direction of securing the stent in the condition of coupling to the insertion element (C).

Fig. 4



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Description

[0001] The present invention relates to angioplasty stents and in particular tackles the problem of coupling the stent to the corresponding insertion element which may be used for location and deployment *in situ* of the stent itself.

[0002] The solution currently most frequently adopted (which is the solution to which reference will be made by way of example in the remainder of the present description) envisages that the insertion element is represented by a catheter provided with a balloon part. Once the stent has been brought onto the site of implantation by catheterism, by distending the balloon it is possible to deploy the stent, bringing it from its radially contracted condition to its radially expanded or extended condition, in which the stent performs the desired action of stenting on the portion of the vessel being treated.

[0003] In the initial years of introduction of methods based upon the use of angioplasty stents, it was quite common to adopt the solution of crimping the stent onto the insertion element (typically a catheter) just prior to the implantation intervention. This was carried out by means of an operation which was usually entrusted to a doctor and/or to the staff that performed the implantation operation.

[0004] Subsequently, the solution that has increasingly gained ground is the one that envisages mounting the stent on the insertion element as final step, carried out at an industrial level, of the process of preparation of an implantation kit consisting of the stent already mounted directly on the insertion element.

[0005] The problems linked to coupling the stents to the corresponding insertion elements are numerous but essentially amount to a number of basic requirements, namely:

- the coupling operation must be sufficiently quick and convenient;
- the operation must not have adverse effects on the operating characteristics either of the stent or of the insertion element; and
- the coupling must be absolutely firm and secure, in such a way as to rule out completely any risk of the stent possibly being undesirably separated from the insertion element, it being necessary for separation to occur (and moreover in a precise and reliable way) only after the stent has been properly positioned and deployed in the site being treated.

[0006] The prior art regarding coupling of stents to corresponding insertion elements is highly extensive.

[0007] For example, from US-A-5 725 519 a solution is known in which a tube, pre-installed together with a stent, is fixed to a component having a tension formation. The tube with the stent extends into the cavity of a second component, which is also provided with a tension formation. The hole of the second component is conical and has a tapered cross section in the direction of the first component. By acting on the two components in the direction that causes them to be moved away from one another, it is possible to pass the tube through the conical hole, so reducing the diameter of the stent, and hence bringing about its radial contraction and coupling onto the insertion element consisting of a balloon catheter.

[0008] From US-A-5 911 452 (see also EP-A-0 867 156) a solution is known that envisages the use of a casing with an inner chamber traversed by a flexible tube. The stent is positioned inside a median portion of the flexible tube and the balloon part of the catheter is inserted into the flexible tube, located inside the stent. A fluid under pressure is injected into the aforesaid chamber which compresses the flexible tube in a circumferential direction, simultaneously compressing the stent so as to grip it (i.e., crimp it) onto the catheter balloon.

[0009] From EP-A-0 903 122 a gripping or crimping tool is known formed by a cylindrical element provided with an external thread and by a rotating collar with an internal thread which engages the aforesaid external thread. The neck part of the cylindrical element is subdivided into a series of jaws subjected to a bias in the direction of divarication. The stent, which is set on the balloon catheter and placed inside the aforesaid jaws in an open condition, undergoes a crimping operation when the aforesaid collar is made to rotate and advance towards the jaws.

[0010] From EP-A-0 873 731 a device is known which is provided with a set of oscillating-arm parts, as well as an annular or tubular element associated to the aforesaid parts. The element in question has an opening, which is on the whole cylindrical and is uniformly compressible in a radial direction inwards when the arm parts oscillate downwards starting from the intermediate portion. In this way it is possible to crimp the stent onto the insertion element.

[0011] From EP-A-0 916 318 another crimping tool is known which comprises a tapered tube mounted coaxially on the catheter in a position adjacent to the distal end of the stent. The aforesaid tube, which can be peeled off, has a first diameter greater than the diameter of the stent, as well as a second diameter smaller than the diameter of the stent prior to crimping. By sliding the tube onto the stent, a radial force is applied, directed inwards, which is distributed evenly on the circumference.

[0012] From EP-A-0 916 319 yet another crimping tool is known which comprises supporting elements set at a distance apart, as well as a helical spring applied at one end to a stem and at the opposite end to one of the supports. The stent/balloon catheter ensemble is inserted into the axial cavity of the spring, with the result that the spring carries out crimping of the stent.

[0013] From US-A-5 893 852 another apparatus is known which comprises a cylindrical casing made up of two cooperating parts. The stent, which is mounted on

the balloon is inserted in a cylindrical cavity the distal part of which has a conical end. The stent is compressed and crimped on the balloon by means of screwing of the two aforesaid parts.

[0014] From US-A-5 860 966 yet another apparatus is known which comprises a casing with a cylindrical membrane that is closed at both ends so as to form a fluid-tight chamber between the membrane and the casing. A fluid is introduced under pressure into the chamber which acts on the membrane until it brings the membrane into a condition of pressure contact with the stent so as to force the stent into a condition of engagement on the balloon.

[0015] From US-A-5 810 838 a solution is known that is based upon the use of a hollow chamber defining a space designed to be filled with fluid and of a compliant tubular sleeve set inside the chamber with one open end communicating with the outside of the casing. The stent is positioned on the corresponding catheter and inserted into the sleeve. The fluid is pressurized so as to compress the sleeve and the stent radially.

[0016] From US-A-6 009 614 a device is known which comprises a cylindrical rigid frame inside which an elastic tube is set. The stent, already mounted on the balloon, is inserted in an opening of the frame. The elastic tube is subjected to axial pressure so as to reduce its length and increase its thickness in the radial direction to effect crimping of the stent.

[0017] From US-A-6 018 857 a tool is known which comprises a grip from which there extends a tube. The stent is set around the tube and is mounted on the balloon by gripping the tool grip and acting in a direction where the grip is pushed away from the catheter.

[0018] From WO-A-00/06052 a crimping tool is known which comprises a stationary plate and a sliding-platform element. A closing plate is hinged to the sliding platform so as to partially overlap the stationary plate in a lowered position. The stent, which is already slightly crimped by hand, is set on the stationary plate starting from a lateral position. The closing plate is displaced into the lowered position so as to withhold the stent in such a way that an external force applied on the closing plate, in combination with the movement of translation of the closing plate itself, produces crimping of the stent.

[0019] From US-A-6 024 737 a device is known which has a compressible bend part that can be compressed in a radial direction inwards so as to obtain crimping of the stent.

[0020] From US-A-6 051 002 a device is known which comprises a pair of grips that form a bend part for withholding the ensemble made up of the stent and the catheter. The ends of the bend are displaced in opposite directions, so reducing the radial dimensions of the bend to crimp the stent on the balloon.

[0021] Yet other documents envisage the possibility of using methods of thermal treatment (so-called "annealing"): in this connection see, for instance, WO-A-99/15106 and US-A-6 063 092.

[0022] Yet other documents specifically tackle the problem of preventing relative sliding between the stent and the catheter. In this connection see, for instance, US-A-5 893 852 (already cited previously), US-A-5 913 871, EP-A-0 855 171, EP-A-0 897 730 and EP-A-0 901 776.

[0023] The purpose of the present invention is to provide a further improvement of the solutions described previously, in particular as regards the complete reliability of the coupling between the stent and the insertion element and the possibility of conferring an extremely reduced profile on the ensemble made up of the stent and the insertion element on which the stent is crimped.

[0024] Both of the characteristics referred to above are of particular importance and interest, above all as regards the methods of direct stenting.

[0025] According to the present invention, the above purpose is achieved thanks to a process having the characteristics specifically recalled in the ensuing claims. The invention also relates to the kit thus obtained.

[0026] The invention will now be described, purely by way of non-limiting example, with reference to the annexed drawings, in which:

- Figure 1 is a general illustration of a stent and the corresponding insertion element prior to coupling.
- Figures 2 to 6 illustrate subsequent steps of the process according to the invention, also with reference to possible variants thereof; and
- Figure 7 is an illustration of the kit obtainable with the process according to the invention.

[0027] In the figures of the annexed drawings the reference S designates, as a whole, an angioplasty stent.

[0028] As is well known (the literature on this subject also in the field of patents is truly imposing), by the term "angioplasty stent" is indicated in general a device having an overall tubular shape which may be introduced in a radially contracted position inside a vessel (typically a blood vessel) affected by stenosis. The subsequent expansion of the stent in the radial direction produces widening of the vessel, with consequent elimination of the stenosis and maintenance of the vessel in a condition of perviousness as a result of the action of support exerted by the stent.

[0029] In the attached drawings, the stent S is therefore illustrated in an altogether schematic way, where only the envelope corresponding to a generic cylindrical tubular form is represented.

[0030] In Figure 1, it has implicitly been assumed that the stent S illustrated has radial dimensions corresponding to those that it has at the end of its process of formation, whatever that process may be. The diameter of the stent S may also be smaller than the diameter that it assumes as a result of its deployment in the implantation site.

[0031] The solution according to the invention is in

fact suitable for being used with practically any type of stent, in a way altogether irrespective of:

- the geometrical and structural characteristics of the stent;
- the criteria of fabrication of the stent (for example, whether the stent is obtained starting from a microtube (so-called hypotubing) or by winding/weaving of yarn; and
- the possible treatments to which the stent itself may or must be subjected prior to or following upon coupling to the insertion element, generically designated by C in the annexed figures.

[0032] The same considerations mentioned previously also apply as regards the material with which the stent has been made. The experiments conducted by the applicant show, however, that the solution according to the invention is suitable for being used to particular advantage in combination with stents made starting from a steel-based material.

[0033] Substantially similar considerations regarding the possibilities of use - which are moreover altogether general - of the solution according to the invention apply also to the insertion element C, here represented schematically (with reference to the solution most widely used, at least at present) at the distal-end part of a balloon catheter.

[0034] In view of the envisaged coupling of the stent S to the said balloon part, in what follows this part will in practice be identified with the insertion element C. It is, on the other hand, altogether evident for a person skilled in the sector that the said insertion element comprises, in association with the part illustrated, also other elements (not illustrated in the drawings, but altogether known in the prior art) that enable the insertion element C, along with the stent S mounted thereon, to be guided onto the implantation site in view of its subsequent deployment, this too being obtained according to known criteria.

[0035] For the purposes of the present invention, it will be sufficient to note that the insertion element C (however made) has in general a diameter d1, which will be assumed, in what follows, as being substantially constant, it hence being also assumed that the insertion element C has a circular or substantially circular section.

[0036] As represented in the figures, the element C corresponds to the typical configuration of winding of the balloon part of a catheter prior to deployment thereof. The reference to this example of embodiment renders altogether evident to a person skilled in the sector the fact that, albeit substantially constant, the diameter identified by the value d1 may in actual fact present, at least at a local level, slight variations due to the characteristics of winding of the balloon.

[0037] The first step of the process according to the invention envisages that the stent S, which is not yet coupled to the insertion element C, is subjected to an action of radial contraction such as to bring its internal diameter to a value d2 at least marginally smaller than the external diameter d1 of the insertion element C to which the stent S is to be coupled.

[0038] This result may be obtained, for example (the person skilled in the sector will appreciate immediately that it is possible to resort to other functionally equivalent solutions) by fitting the stent S on a pin or stem 1 consisting, for instance, of a cylindrical body made of rigid or substantially rigid material having an external diameter equal to d2 and, preferably, a cylindrical cross section.

[0039] The operation of radial compression of the stent S aimed at bringing the internal diameter thereof to the value d2 is schematically illustrated in the sequence of Figures 2 and 3.

[0040] As an alternative to the solution described herein, purely by way of example, the aforesaid action of radial contraction may be obtained with any known solution, including the various solutions cited in the introductory part of the present description, and this, even though the said previous solutions are in actual fact aimed at obtaining radial contraction of the stent S so as to bring about its crimping directly on the insertion element.

[0041] On the other hand, with the solution according to the invention, the said action of radial contraction is performed before the stent S is coupled to the insertion element C.

[0042] As regards what is to be understood, with reference to the diameter d2, by diameter "at least marginally smaller" than the diameter of the insertion element C, the experiments conducted by the applicant show that, even though the results of the invention may be achieved for any value of d2 smaller than d1, particularly advantageous results are achieved when the diameter d2 is at least 5% smaller than the diameter d1. Particularly satisfactory results may be achieved (above all with reference to stents S made of steel-based materials) when the diameter d2 is approximately 25% smaller than the diameter d1.

[0043] Without wishing to be tied down to any specific theory in this regard, the applicant has reason to believe that, if said preferred values are chosen, as a result of the radial contraction or compression of the stent S, there will arise, following upon the subsequent operation of application on the insertion element C (an operation that may be carried out according to criteria described in greater detail in what follows) states of constraint of particular importance, which are able to ensure the desired degree of coupling of the stent S to the element C.

[0044] There exists of course the possibility that the action of radial contraction of the stent S, here represented as performed by gripping of the stent S on the pin or stem 1, is obtained and/or is accompanied by a possible heat treatment.

[0045] Figure 3 refers, in deliberately schematic terms, to a solution in which the operation that leads to

a reduction in the radial dimensions of the stent S so that the external diameter of the latter corresponds to the value d2 is obtained as a result of an action of radial compression which is assumed as being ideally distributed in a uniform way over the entire periphery of the stent S and as being obtained by means of radial-compression tools 2.

[0046] As has already been said, the above tools may be made, for example, according to the same general criteria described in various documents of the prior art cited in the introductory part of the present description.

[0047] From Figure 3 it will be noted that the tools 2 have been deliberately represented as "shorter" than the overall axial extension of the stent S, hence such as not to involve the ends of the stent S directly in their action.

[0048] The above representation, which is deliberately schematic, intends to recall the fact that the aforesaid operation of reducing the radial dimensions does not need to be performed over the entire development of the stent S, but may involve just one part of the stent S, for example the central portion (as in the embodiment illustrated herein), or just the end portions (this according to an arrangement which is complementary with respect to the one illustrated in Figure 3), or even one or more portions the dimensions of which and/or the distribution of which over the length of the stent are determined, among other things, according to the characteristics of the stent S and/or of the element C.

[0049] Again regarding the aforesaid applicational requirements, it is possible, according to a further variant embodiment of the invention (not specifically illustrated in the drawings), to cause the action of reduction of the internal diameter to the value d2 to involve only certain portions of the peripheral development of the stent S, and not the entire circumference thereof.

[0050] In the latter case, for example, the tool or tools 2 in practice assume the form of punches designed to advance radially towards the body of the stent S so as to produce reduction of the internal diameter of the latter to the value d2 only in those areas that are affected by the action of the punches.

[0051] In any case it will be appreciated that an important characteristic of the solution according to the invention is represented by the fact that the action of radial contraction of the stent S designed to bestow on the stent itself dimensions such as to enable its coupling on the insertion element C is performed prior to, and not after, mounting of the stent S on the element C.

[0052] The subsequent steps of the process according to the invention thus envisage that the stent S, the internal diameter of which has been brought to the value d2, is then fitted onto the insertion element C, the external diameter of which is equal to d1.

[0053] The foregoing is carried out in conditions in which the diameter d2 is "at least marginally smaller" than the diameter d1. For the meaning attributed to the term "at least marginally smaller", refer to the note of a terminological nature expressed previously.

[0054] As in the case of the operation of reduction of the internal diameter of the stent S to the value d2, in order to set the stent S on the insertion element C it is possible to resort to various solutions, all of which are in themselves known.

[0055] The sequence of Figures 4 and 5, on the one hand, and Figures 4 and 6, on the other, refer to two possible solutions which have been tested with successful results by the present applicant and which are essentially based upon causing the stent S to advance longitudinally with respect to the insertion element C as a result of a relative movement of sliding.

[0056] The aforesaid movement may be obtained, for example, by "feeding" the distal end T of the catheter, of which the element C forms part, inside the stent T, and then exerting, on the said distal end T, a careful tensile action (by means of a tool not specifically illustrated but of a type in any case known, for instance of the nature of some of the solutions described in the documents cited in the introductory part). During this process, the stent S is withheld (by an equally careful action of retention in order to prevent the stent getting damaged) by means of tools 3, which are also of a conventional type.

[0057] As has already been said, the above-mentioned movement of insertion derives from a relative motion of the stent S and the element C. This movement may therefore be obtained either by holding the stent S stationary and sliding the element C inside it, or by holding the element C stationary and sliding the elements 3 which carry the stent S with them causing the stent S to slide onto the outside of the element C, or again by means of a movement involving both the element C and the stent S together.

[0058] In particular, the action of "feeding" of the stent S onto the element C is preferably facilitated by means of a coupling insert 4 which may, for example, consist of a sort of sheath which comprises a portion having a conical shape or the shape of a truncated cone and is made of a material having a low coefficient of friction (for example, polytetrafluoroethylene or similar materials) and a reasonable degree of flexibility, also in relation to its thickness.

[0059] The insert 4 is set on the end of the element C starting from which the sliding movement of the stent S onto the element C is performed.

[0060] It will moreover be appreciated that, in the case where the element C is made up of the balloon of a catheter, the element 4 (which is generally eliminated and removed once the desired coupling of the stent S and of the element C has been achieved) has a shape that adapts to the approximately conical, or anyway tapered, shape which the aforementioned end of the balloon normally already has in any case (see, for example the right-hand part of Figure 1).

[0061] Figures 5 and 6 aim at highlighting the fact that the action of coupling between the stent S and the element C consists essentially in two possible effects which

can be exploited both as alternatives and in combination, according to the specific applicational requirements.

[0062] In particular, Figure 5 refers to a situation in which while the stent S is being fitted onto the element C it is not subjected to an action of containment in a radial direction.

[0063] Since, as has already been seen, the internal diameter d2 of the stent S is at least marginally smaller than the external diameter d1 of the element C, in these conditions the coupling movement is performed (assuming, from a purely conceptual standpoint, that the element C is radially incompressible) as a result of a slight divarication of the stent S which brings the internal diameter of the latter from the value d2 to the value d1.

[0064] Figure 6 refers to a situation in which, during the aforesaid movement of insertion, the stent S undergoes an action of radial containment, for instance by setting on it a sheath 5 (designed so that it can subsequently be removed) made - by means of a choice of material consisting, for example of a silicon rubber, polyurethane, polytetrafluoroethylene - and/or according to the thickness in such a way as to prevent, or at least substantially prevent, radial dilation of the stent S.

[0065] In the above situation, the coupling action is achieved as a result of a radial contraction of the element C, the external diameter of which passes from the value d1 to the value d2.

[0066] In actual fact, the intrinsic physical characteristics of the elements concerned mean that, in practice, at least in the case represented in Figure 5, in which the stent S is not subjected to an action of radial containment, the desired coupling involves both a radial expansion of the stent S and a radial compression of the element C. In the final coupling condition, the internal diameter of the stent S and the external diameter of the element C end up coinciding with one another at a value which is intermediate between the values d1 and d2.

[0067] The same may apply also in the case of the solution of Figure 6, at least in those cases in which the action of containment represented as exerted by the sheath 5 is not absolute but is in any case such as to enable an albeit modest dilation of the stent S.

[0068] Where the aim is in any case to minimize the end profile of mounting of the stent S on the element C, it may be desirable for the above-mentioned action of radial containment of the stent S to be absolute; consequently, the movement of insertion is performed exclusively by means of a radial contraction of the element C. Of course, once the containment element 5 is removed, the elastic reaction of the element C aimed at producing radial expansion of the latter, is in any case such as to bring about a corresponding expansion, albeit of an extremely contained amount, of the stent S.

[0069] In any case, once the final condition of coupling has been reached, as represented in Figure 7, the final result is given by the fact that the stent S is withheld on the insertion element C principally as a result of the states of constraint existing within the structure of the stent S, which tend to bring the stent S back towards the condition imparted on it following upon the operation represented in Figure 3, i.e., following upon the action of radial contraction that brought its internal diameter to the value d2, which is smaller than the value of the diameter d1 of the element C on which the stent S was subsequently fitted.

[0070] The tests carried out by the present applicant show that, above all in the case where the diameter d2 is at least 5% smaller, and preferably approximately 25% smaller, than the diameter d1, the intensity of the forces deriving from the above-mentioned states of constraint is somewhat marked, and hence such as to ensure a firm anchorage of the stent S on the element C and such in any case as to prevent undesirable separation of the stent S from the element C, also in view of the possible performance of direct-stenting interventions. The foregoing is achieved without any need to resort to further forms of treatment, such as heat treatment, of the kit schematically represented in Figure 7 and consisting of the stent S mounted on the element C.

[0071] Persons skilled in the sector will immediately appreciate that in the solution according to the prior art, where to achieve coupling with the element C the stent is subjected to radial compression after being mounted on the element C or while it is being mounted on the element C, the residual states of constraint that remain in the stent S act in an exactly opposite direction, producing a mechanism of elastic return which tends to dilate the stent S, bringing its radial dimensions back towards the value that these dimensions had before the stent S was compressed on the element C.

[0072] Consequently, in such solutions according to the prior art the states of constraint tend, at least in a latent way, to operate in the direction of favouring separation of the stent S from the element C.

[0073] Instead, in the solution according to the invention, the above states of constraint tend to bring the stent S towards the radially contracted position (i.e., towards the internal diameter d2) which had previously been imparted on it during the step represented in Figure 3. The aforesaid states of constraint thus act in the direction of favouring anchorage of the stent S on the insertion element C. At the same time, the process facilitates, if indeed it does not actually produce spontaneously, the formation of swollen end portions W of the element C (which is usually made of elastic material, such as silicon rubber or the like) such as to perform a further action of longitudinal containment of the stent S on the element C.

[0074] Of course, without prejudice to the principle of the invention, the details of construction and the embodiments may vary widely with respect to what is described and illustrated herein, without thereby departing from the scope of the present invention.

Claims

1. A process for coupling an angioplasty stent (S) to a corresponding insertion element (C), in which said angioplasty stent (S) is subjected to an action of radial contraction,
   characterized in that said stent (S) is subjected to said action of radial contraction before being set on said insertion element (C).

2. The process according to Claim 1, **characterized in that** said action of radial contraction is carried out by imparting on said stent (S) a given diametral dimension (d2) at least marginally smaller than the homologous diametral dimension (d1) of said insertion element (C).

3. The process according to Claim 2, **characterized in that** said given diametral dimension (d2) is at least 5% smaller than said homologous diametral dimension (d1) of said insertion element (C).

4. The process according to Claim 2, **characterized in that** said given diametral dimension (d2) is chosen as being about 25% smaller than said homologous diametral dimension (d1) of said insertion element (C).

5. The process according to any one of the preceding claims, **characterized in that**, after said action of radial contraction, said stent (S) is fitted onto said insertion element (C), thus bringing about at least one of the following conditions:

   - divarication of said stent (S); and
   - contraction of said insertion element (C).

6. The process according to Claim 5, **characterized in that** it comprises the operation of exerting, on said stent (S), an action of radial containment aimed at countering divarication of said stent (S) while the latter is being filled onto said insertion element (C).

7. The process according to Claim 5 or Claim 6, **characterized in that** said stent (S) is fitted onto said insertion element (C) as a result of a movement of relative axial sliding which causes said insertion element (C) to slide inside said stent (S) and said stent (S) to slide outside said insertion element (C), the aforesaid sliding movement being performed starting from a given end of said insertion element (C).

8. The process according to Claim 7, **characterized in that** it comprises the operation of setting, at least on said given end of said insertion element (C), a guiding insert (4) having a shape as a whole diverging in the direction of the relative sliding of said stent (S) on said insertion element (C).

9. The process according to Claim 8, **characterized in that** said guiding insert (4) is made of a material with a low coefficient of friction and/or provided with good characteristics of flexibility.

10. The process according to Claim 8 or Claim 9, **characterized in that** said guiding insert (4) is removed once coupling of said stent (S) with said insertion element (C) has been achieved.

11. The process according to any one of Claims 7 to 10, **characterized in that** said movement of relative sliding is obtained by means of an action of tension exerted on a distal appendage (T) of said insertion element (C).

12. The process according to any one of the preceding claims, **characterized in that** said stent (S) is made of a steel-based material.

13. The process according to any one of the preceding claims, **characterized in that** said insertion element (C) is the balloon part or a balloon catheter.

14. The process according to any one of the preceding claims, **characterized in that** said action of radial contraction is exerted over the entire development of said stent (S).

15. The process according to any one of Claims 1 to 13, **characterized in that** said action of radial contraction is exerted only on a part of said stent (S).

16. The process according to Claim 2, **characterized in that** it comprises the operations of:

   - providing a forming stem or pin (1) having a diameter corresponding to said given diametral dimension (d2); and
   - exerting said action of radial contraction by forcing at least part of said stent (S) into contact with said forming stem or pin (1).

17. An implantation kit comprising an angioplasty stent (S) coupled to a corresponding insertion element (C) by means of the process according to any one of the preceding claims.

18. An implantation kit comprising:

   - an angioplasty stent (S); and
   - a corresponding insertion element (C);

   said angioplasty stent (S) being coupled to said corresponding insertion element (C), said implantation kit being **characterized in that** in the structure of

said stent (S) there are present states of constraint acting in the direction of inducing radial contraction of said stent (S) and consequent retention of said stent (S) on the insertion element (C).

19. The implantation kit according to Claim 18, **characterized in that** said stent (S) is made of a steel-based material.

20. The implantation kit according to Claim 18 or Claim 19, **characterized in that** said insertion element (C) is constituted by the balloon part of a balloon catheter.

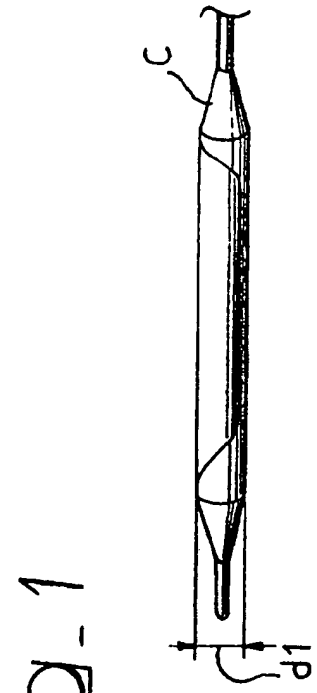


Fig. 1

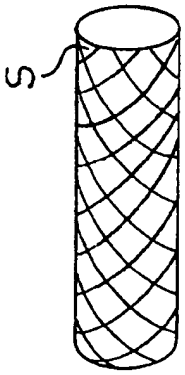


Fig. 2

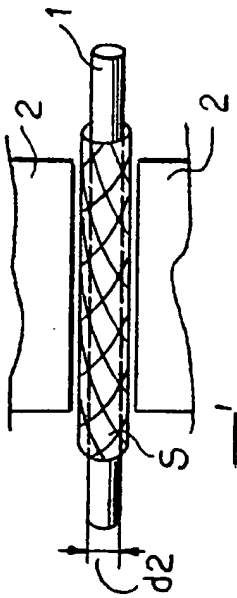
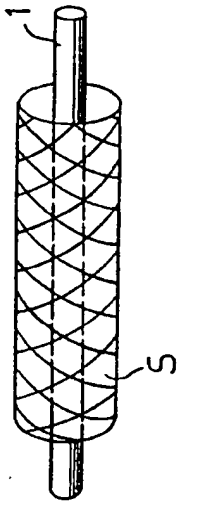


Fig. 3



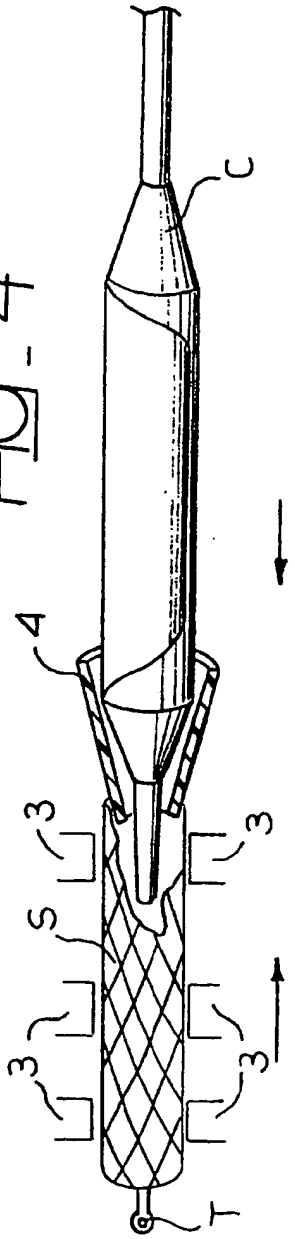


Fig. 4

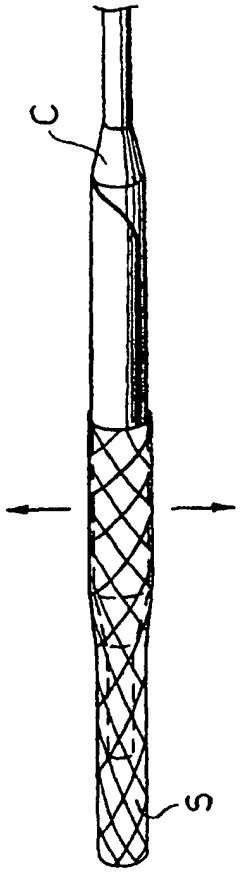


Fig_5

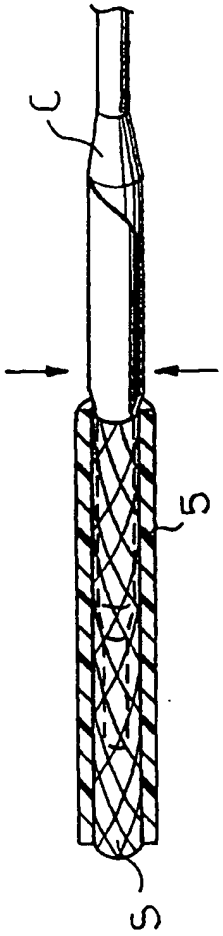


Fig_6

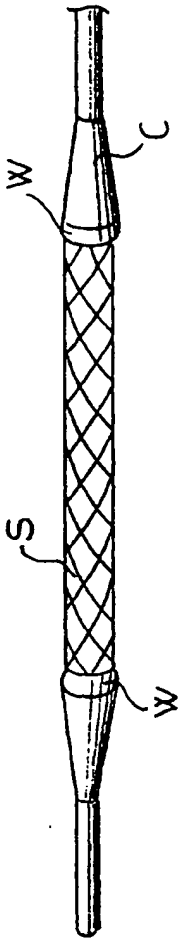


Fig_7